MAY 17 2002

K020113

EXHIBIT 2

Vector Research & Development
1909 70th Ave W, #C
University Place, WA 98466
Tel (253) 564-5084
Fax (253) 564-4927
December 13, 2001
Contact: Brent Bigler

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Vector F Series" High-speed Dental Handpieces.
   Classification Name: **EFB**
   Common/Usual Name: HANDPIECE, AIR-POWERED, DENTAL

2. Equivalent legally marketed device: Star Dental 430 Series High Speed Handpiece, K982593 and KaVO 625/634 Handpieces, K760929

3. Indications for Use (intended use) The device is an air-powered dental handpiece for use by a trained professional in general dentistry.

4. Description of the Device: The Vector F series handpiece shares virtually all specifications and design characteristics of the predicate devices. This was done intentionally by the designers and engineers. The only major design or engineering change is the strength of the autochuck mechanism. By increasing the spring strength we have created and even safer version of the KaVo 625CD. By increasing the bur retention strength form 6 lbs (as with the predicate device) to 8 lbs (Vector F series) we have been able to vastly reduce the odds of a bur prematurely ejecting for the handpiece. A few minor changes to the predicate device which do not affect the performance but we feel make the handpiece even safer are as follows: Reduction in the weight of the handpiece to 2 oz.. This reduces operator hand fatigue. Softened the knurling on the handle. This allows dirt, blood and saliva to be more easily removed from the body shell of the handpiece thus allowing better conformity to sterilization procedures. It also provides better tactile sense to the operator while wearing gloves.

5. Safety and Effectiveness, comparison to predicate device:

Element of Comparison	StarDental 430 Series, K982593; KaVO 625/634 Handpieces, K760929	Vector F Series
Intended Use	General dentistry by trained professional.	SAME
Materials: Handpiece housing Turbine Housing Turbine housing cap Plating	 Copper-tin Bronze Nickel silver CDA alloy Stainless steel Chrome	SAME
Energy source	Air pressure, 30-32 psi	SAME, 30-35 psi
Sterilization	Steam autoclave or chemical vapor	SAME

6. Conclusion: In all respects, the Vector F Series High-speed Dental Handpieces are substantially equivalent to one or more air-powered dental handpieces currently marketed in the USA. The handpieces are constructed of identical materials and conform to applicable ISO standards. The ability to repeatedly sterilize the devices has been confirmed through performance of a validation protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2002

Vector Research & Development
C/O Mr. Daniel Kamm
Kamm & Associates
P. O. Box 7007
Deerfield, Illinois 60015

Re: K020113
Trade/Device Name: Vector F Series High-Speed Dental Handpieces
Regulation Number: 872.4200
Regulation Name: Dental Handpiece
Regulatory Class: I
Product Code: EBF
Dated: March 25, 2002
Received: March 26, 2002

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cucinotta for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020113

j) Indications for Use

510(k) Number_____

Device Name: "Vector F Series" High-speed Dental Handpieces.

Indications for Use: The device is an air-powered dental handpiece for use by a trained professional in general dentistry.

_____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020113